1642

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Philip John Burke and Richard John Knox

Serial No.: 09/445,865 Art Unit: 1642

Filed: February 11, 2000 Examiner: G. Nickol

For: *THERAPEUTIC SYSTEMS*

#8
KO
3-31-01

Assistant Commissioner for Patents
Washington, D.C. 20231

RESPONSE TO RESTRICTION REQUIREMENT

Sir:

Responsive to the Office Action mailed February 13, 2001 please consider the following remarks. It is believed that no fee is required with this submission. However, should a fee be required, the Commissioner is hereby authorized to charge any fees to Deposit Account No. 01-2507. To facilitate this process, Applicants enclose a duplicate of this document.

Remarks

The examiner has noted that there are 16 groups to which the claims have been divided on the basis of inventive unity. The applicants respectfully submit that the examiner has formulated 17 groups and not 16. It appears that the examiner has numbered two different groups as "Group 3".

Response to Restriction Requirement

In the Office Action mailed February 13, 2001, the claims were divided into 17 groups, Group I, claims 1-7, 24, drawn to a protein compound comprising a target cell-specific portion

and human NAD(P)H:quinone reductase 2; Group II, claims 1-7, 24, drawn to a polynucleotide encoding NZO2, variant, fragment, fusion, or derivative; Group III, claims 8-12, 24, drawn to a recombinant polynucleotide comprising a target cell-specific promoter operably linked to a polynucleotide encoding NQO2; Group IV, claims 13-17, drawn to a therapeutic system comprising a protein compound comprising a target cell-specific portion and human NAD(P)H:quinone reductase 2; Group V, claims 13-17, drawn to a therapeutic system comprising a polynucleotide encoding NQO2, variant, fragment, fusion, or derivative; Group VI, claims 13-17, drawn to a therapeutic system comprising a target cell-specific promoter operably linked to a polynucleotide encoding NQO2; Group VII, claims 18-23, drawn to a method of treating a patient with a target cell to be destroyed comprising administering a protein compound comprising a target cell-specific portion and human NAD(P)H:quinone reductase 2; Group VIII, claims 18-23, drawn to a method of treating a patient with a target cell to be destroyed comprising administering a polynucleotide encoding NQO2, variant, fragment, fusion, or derivative; Group IX, claims 18-23, drawn to a method of treating a patient with a target cell to be destroyed comprising administering recombinant polynucleotide comprising a target cell-specific promoter operably linked to a polynucleotide encoding NQO2; Group X, claims 25-28, drawn to a method of using a protein compound comprising a target cell-specific portion and human NAD(P)H:quinone reductase 2; Group XI, claims 25-28, drawn to a method of using a polynucleotide encoding NQO2, variant, fragment, fusion, or derivative; Group XII, claims 25-28, drawn to a method of using a recombinant polynucleotide comprising a target cell-specific promoter operably linked to a polynucleotide encoding NQO2; Group XIII, claims 29-33, 40,

drawn to a method of treating a human patient with a target cell to be destroyed wherein the target cell expresses NQO2; Group XIV, claims 34-35, drawn to a therapeutic system comprising a prodrug and nicotinamide riboside; Group XV, claim 36-37, drawn to a method of using a therapeutic system comprising a prodrug and nicotinamide riboside; Group XVI, claim38, drawn to a method of using a prodrug in the manufacture of a medicament for treating a human patient; and Group XVII, claim 39, drain to a kit comprising a means for determining whether a target cell to be treated expresses NQO2 and NRH or an analogue thereof which can pass reducing equivalents to NQO2. In response, applicants elect Group XII (renumbered as Group XIII, due to two Group 3), claims 29-33, and 40 with traverse.

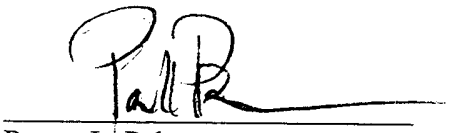
Applicants traverse the restriction requirement as currently set forth for the following reasons. To be valid, a restriction requirement must establish both that (1) the "inventions" are either independent or distinct, and (2) that examination of more than one of the "inventions" would constitute a burden to the Examiner. The Office Action mailed February 13, 2001, sets forth reasons why the "inventions" are distinct (i.e. the inventions listed as Groups 1-17 do not relate to a single concept under PCT Rule 13.1 because under PCT Rule 13.2 they lack the same or corresponding special technical features).

All of the claims in the present application share the single inventive concept that NQO2 can activate prodrugs (such as CB1954) in the presence of substrates such as NRH and analogues thereof. This inventive concept is at the core of the claimed therapeutic systems and methods of treating human patients with a target cell expressing NQO2 and administering to the patient a prodrug that is converted to exert cytotoxicity by the action of NQO2 and NRH or analogue

thereof. The examiner's Groups 12, 13 and 14 particularly share the single inventive concept that NQO2 can activate prodrugs in the presence of substrates such as NRH and its analogues. Applicants respectfully note that there was not a lack of unity objection raised in the International Preliminary Examination Report mailed on May 6, 1999.

Applicants would therefore greatly appreciate consideration of the claims of groups XII, XIII, and XIV (renumbered as XIII, XIV and XV), claims 29-37 and 40.

Respectfully submitted,



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Date: March 13, 2001

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I hereby certify that this paper, along with any paper referred to as being attached or enclosed, is being deposited with the United States Postal Service on the date shown below with sufficient postage as first-class mail in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

Jean Hicks

Date: March 13, 2001